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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>09/211,507</b>	Applicant(s) <b>Hirsch</b>
	Examiner <b>Christopher Tate</b>	Group Art Unit <b>1651</b>



Responsive to communication(s) filed on Nov 13, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-11 and 24-43 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-11 and 24-43 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 4 & 14

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

Applicant's election of Group I, claims 1-11 and new claims 24-43, in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant's further election of the odorant species being a mixture of a licorice-based odorant and a cucumber-odorant in Paper No. 13 (in which new claim 43 was added) is also acknowledged.

Claims 1-11 and 24-43 are presented for examination on the merits.

#### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-11 and 24-43 are rejected under 35 U.S.C. 101 for the following reasons:

Although it is well accepted in the art that mammals including humans respond to certain odors (e.g., females to male odors including male pheromones/musks - see, e.g., various IDS references including Durden-Smith et al., 1983) resulting in enhanced sexual arousal (which would inherently increase blood flow to the vagina) and/or in-heat, it is not reasonably believable to one of skill in the art of human sexuality that the commonly encountered diverse odors instantly disclosed/claimed (e.g., Good and Plenty® licorice candy odor and/or cucumber odor, baby

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powder odor, Chanel No. 5 perfume, banana nut bread odor, pumpkin pie odor, etc.) would have such an effect (or, alternatively, have the opposite effect). If this were the case, many women would inherently be experiencing this effect on a frequent basis (e.g., putting baby powder on their babies, preparing banana nut bread, eating Good and Plenty® candy, wearing Chanel No. 5, etc. - as all of these commonly encountered products emit odors).

Although the instantly disclosed examples demonstrate such an effect, those skilled in the art of human sexuality are unlikely to accept the data as being correlatable to providing such an effect. The observed female sexual arousal effect (which apparently correlates to an inhaled-type female Viagra® - i.e., causing increased blood flow to the vagina) or, alternatively, providing the opposite effect (causing decreased blood flow thereto- it is noted in several instances that using the same odorant or mixture of odorants that cause an increased blood flow to the vagina to some females also cause a decrease in blood flow to the vagina in other females) is therefore considered to be, at most, a placebo-effect. Please note that the placebo-effect, which is a psychophysiological effect to a given treatment (i.e., the administered agent, per se, does not cause the observed effect), is a well documented phenomenon which has been repeatedly shown to be responsible for the observed functional effects shown by patients in numerous clinical trials.

Accordingly, given the unbelievable nature of overall instantly disclosed/claimed invention, one of skill in the art of human sexuality would reasonably conclude that the observed effects are the result of such a placebo-effect and not caused by the claimed commonly encountered odorants themselves (or mixtures thereof).

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 and 24-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

For the same reasoning as set forth above under USC 101, those of skill in the art of human sexuality are unlikely to accept the data as being correlatable to providing the claimed effect (which apparently correlates to an inhaled-type female Viagra® - i.e., causing increased blood flow to the vagina) or, alternatively, providing the exact opposite effect (causing decreased blood flow thereto- it is noted in several instances that using the same odorant or mixture of odorants that cause an increased blood flow to the vagina to some females also cause a decrease in blood flow to the vagina in other females) via inhalation of the instantly claimed odorants (or mixtures thereof). Again, the observed female sexual arousal effect is considered to be, at most, a placebo-effect.

Accordingly, the claimed invention is deemed non-enabled because the instantly claimed functional effect resulting from inhaling the recited odorants is not a reasonably believable utility to those of skill in the art of human sexuality for the reasons set forth above, as also discussed in greater detail under USC 101.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 and 24-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The independent claims (i.e., claims 1, 26, 32, and 33) are rendered vague and indefinite by the following phrases: "altering vaginal blood flow" and "in an amount effective to alter vaginal blood flow". These phrase are confusing as they seem to be defining external blood flow which seemingly is flowing away from the vagina (i.e., menstruation) instead of internal blood flowing to the vagina. It is suggested that "altering vaginal blood flow" and "effective to alter vaginal blood flow" be omitted and replaced with --altering blood flow to the vagina-- and --effective to alter blood flow to the vagina--, respectively, to more clearly define this essential limitation (other recitations drawn to altering vaginal blood flow in these claims and in independent claims are also unclear for the same reasoning and should, therefore, also be appropriately amended; it is also suggested that the Title be changed accordingly).

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

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Please note for the art rejections below, the elected species is free of the art (i.e., a mixture of cucumber- and licorice-based odorants). Therefore, another odorant from those recited: a floral aldehydic perfume odorant, was selected by the examiner (as well as an overall art-accepted odorant - e.g., pheromone/musk: over the broad independent claims of claims 1 and 33 and certain dependent claims therefrom). Thus, the claims have been examined over the art only insofar as they read on a floral aldehydic perfume odorant (as well as on an art-accepted sexual arousal odorant - e.g., pheromone/musk smell).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

a person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 7, 9, 33, 35-37, 39-42 are rejected under 35 U.S.C. 102(b) as being anticipated by the recognized state of the art.

As readily admitted by applicant, "a floral-aldehydic perfume odorant" includes the perfume "Chanel No. 5" (see, e.g., page 4, lines 12-13 of the instant specification).

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Accordingly, a woman wearing a floral-aldehydic perfume odorant such as Chanel No. 5, which has been on the market for many years prior to the filing date of the instant invention, would inherently and necessarily inhale the perfume odor and, thus, also inherently experience the instantly claimed functional effect (i.e., altered vaginal blood flow). Please note that the instantly claimed method is a one-step method - i.e., inhaling the claimed odorant by a female individual. Thus, the prior art method above inherently must function as claimed because the same composition is being inhaled by a female individual (see, e.g., In re Best, 195 USPQ 430, 433 - CCPA 1977). The particular claimed functional effects would also inherently occur upon inhalation of Chanel No. 5. Thus, the reference is deemed to anticipate the instant claims above.

Claims 1, 33, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Cutler et al. (US 5,155,045).

Cutler teaches administering male axillary secretion from a male to the nasal region of a female (acts as an odorant) to "alter vaginal blood flow". Baseline measurements were made with respect to the female participants vaginal blood flow prior to administering the male axillary secretion (see, e.g., col 3, lines 54-63, col 9, line 59 - col 19, line 54). Note: based upon the various physiologic effects induced in females by male axillary secretion, the instantly disclosed effect - i.e., increased blood flow to the vagina due to female nasal exposure to these male axillary secretions (pheromones) is also deemed to inherently occur. Therefore, the reference is deemed to anticipate the instant claims above.

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Claims 1, 2, 4, 9, 33, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Durden-Smith et al. (*Sex and the Brain*, 1983).

As evidenced by Durden-Smith et al. (among others), it is well-recognized in the art of human sexuality that male sex hormones (pheromones) and/or male secretions such as human sweat - as well as compounds therein (such as alpha-androstenol, which is related to musk) enhance sexual attraction/arousal in females (see entire document - e.g., pages 216-222). Accordingly, a female would inherently experience the instantly claimed functional effect (i.e., altered vaginal blood flow) via inhaling these well recognized components.

Again, please note that the instantly claimed method is a one-step method - i.e., inhaling the claimed odorant by a female individual. Thus, the prior art method above inherently must function as claimed because the same composition is being inhaled by a female individual (see, e.g., In re Best, 195 USPQ 430, 433 - CCPA 1977). The particular claimed functional effects would also inherently occur upon inhalation of male sex hormones (pheromones) and/or aromas found in male secretions such as human sweat (including compounds therein such as alpha-androstenol and/or musk).

Therefore, the reference is deemed to anticipate the instant claims above.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 9-11, 33, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durden-Smith et al. (*Sex and the Brain*, 1983).

The Durden-Smith et al. reference is relied upon for the reasons discussed above.

Durden-Smith et al. do not expressly teach the amount of odorant nor the time period for inhaling such an odorant. However, determining the result-effective concentration range and inhalation duration of (exposure to) such male pheromones and/or isolated compounds (e.g., alpha-androstenol), as beneficially taught by Durden-Smith et al. (among others), so as to induce sexual arousal in a female individual is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skill artisan.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

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### Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached at (703) 308-4743. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1651 is (703) 308-4242.



Christopher R. Tate  
Primary Examiner, Group 1651  
January 30, 2001